TN Department of Health

MEMBERS PRESENT

Dr. Melanie Blake, Board of Medical Examiners, Chairperson
Ms. Lisa Tittle, Board of Pharmacy
Dr. R. Michael Dickenson, Board of Pharmacy
Dr. Sheila Schuler, Podiatry Board
Dr. Robert Simpson, Board of Veterinary Medicine
Dr. Linda Tharpe, Board of Optometry
Mr. Brett Reeves, Committee on Physician Assistants
Ms. Juanita Turnipseed, Board of Nursing
Dr. Shant Garabedian, Osteopathic Board

STAFF PRESENT

Dr. D. Todd Bess, Director of Controlled Substance Monitoring Database
Dr. Mitchell Mutter, Medical Director for Special Projects
Mr. Andrew Coffman, Attorney, Office of General Counsel (OGC)
Ms. Debora Sanford, Clinical Application Coordinator
Ms. Michelle Long, Assistant Commissioner, and Interim Director, Office of Investigations
Ms. Tracy Bacchus, Administrative Assistant

MEMBERS ABSENT

Dr. Katherine Hall, Board of Dentistry
Mr. Robert Ellis, Board of Medical Examiners

The CSMD Committee convened on Monday, February 04, 2019, in the Iris Room, 665 Mainstream, Nashville, TN. Dr. Blake called the meeting to order at 9:00 a.m. and the members introduced themselves.

Dr. Blake communicated to the group the meeting is being live streamed so please speak into the microphone and make sure the green light is on to indicate microphone is active.

Minutes

Dr. Blake asked had everyone read the minutes from the meeting on October 02, 2018, and is there a motion to approve the minutes.

- Dr. Garabedian made the motion to accept the minutes from the October 02, 2018 committee meetings, and Dr. Tharpe seconded the motion,
- Move by acclimation the minutes were approved.

Office of Investigation – Michelle Long

- Updated the committee on pain management clinics and over prescribing complaints
  - 126 pain management clinics which is significantly down due to good legislation;
  - TDH denied five pain clinics; and
  - One (1) was revoked in 2018
- Number of complaints for 2018
  - Complaints received was 2,513
    - 2,480 disposed/closed in some manner,
    - 110 received for overprescribing,
      - 34 overprescribing complaints closed in Office of Investigations and transferred to OGC where a case is opened,

- 12 cases resulted in revocation, voluntary surrender, or suspension of a practitioner's license,
- 11 practitioners were placed on probation,
- Nine (9) practitioners were publicly reprimanded.

- OGC opened 18 new cases against prescribers, and 5 new cases against pain clinics.

- Updated the committee on the Office of Investigation complaint process (which is a complaint driven)
  - The complaints gets triaged by a members of the Office of Investigation,
  - During the triage they get assigned a benchmark based on that review and the allegation;
    - 5-7 days
    - 30 days
    - 60 days
    - 120 days
    - 150 days
  - Phase one review – complaint is reviewed by a consultant and a member of TDH legal team to determine if it needs to go to the field for further investigation;
  - Phase two review – complaint is reviewed again by a consultant and a member of TDH legal team to determine if the information gathered is enough for complaint to be transferred to OGC where a case will be opened.
    - Closed then process ends
    - Sent to OGC becomes a case

Office of General Counsel - Andrew Coffman

- Mr. Coffman reported prescribing cases for September 2018 through December 2018
  - Six (6) Nursing cases
  - Four (4) BME cases
  - Two (2) Dentistry cases
    - Discussed Dr. Lubovich case
  - One (1) Physician Assistant case
  - One (1) Veterinary case
    - Discussed Dr. Riddle case
  - One Pain Management Clinic case
- Updated the committee on the Kentucky project
  - Received approval from STS, central procurement, and contracts,
  - TDH had so many changes in the agreement it had to be sent back to Kentucky for approval
- Mr. Coffman updated the committee on the Commissioner CSMD Rules and the CSMD Advisory Rules

TN Department of Health

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Commissioner's CSMD Rules

Rule 1 – Reporting to the Database

(1) Dispensing healthcare practitioners or their agents shall submit the data that is required by T.C.A. § 53- 10-305 in one of the following forms: (a) An electronic device compatible with the Committee's receiving device or the receiving device of the Committee's agent; or (b) Other electronic or data format approved by the Committee. Veterinarians shall not be required to use a computerized system in order to submit required information to the database. Instead veterinarians may elect to submit information to the database by any appropriate method set forth in the Tennessee Controlled Substance Database Data Collection Manual.

(2) The information to be included in the database shall be submitted each business day and no later than the close of business on the business day after dispensing for all controlled substances as set forth in the Prescription Safety Act of 2016. Consistent with the Prescription Safety Act of 2016, veterinarians shall only be required to submit information to the database every fourteen days.

(3) The dispensing healthcare practitioner or its agent, excluding a veterinarian, shall transmit or enter into the data collection application the data that is required pursuant to T.C.A. § 53-10-305 in the 2009 version of the Telecommunications Format for Controlled Substances established by the American Society for Automation in Pharmacy (ASAP). Beginning on July 1, 2019, the dispensing healthcare practitioner or its agent, excluding a veterinarian, shall transmit or enter into the data collection application the data that is required pursuant to T.C.A. § 53-10-305 in the 2018 version 4.2A of the Telecommunications Format for Controlled Substances established by the ASAP. The committee shall have the power to grant a waiver of the requirement to report or submit data in the 2016 version 4.2A of the Telecommunications Format for Controlled Substances established by the ASAP upon a showing of hardship. Such waiver shall be good for up to two (2) years. The dispenser shall report, at minimum, all required fields even when reporting using alternative method as per waiver.

(4) Each controlled substance prescription required to be reported to the database shall be serially numbered.

(5) Each dispenser or dispenser's agent shall, regarding each controlled substance in Schedules II-V dispensed, submit to the database all of the following information in accordance with the guidance in the CSMD Data Collection Manual:

Dispenser Information

(a) Dispenser NPI Number, if available
(b) Either an NCPDP or NABP Provider ID, if available, as set forth in the CSMD Data Collection Manual
(c) DEA Number;
(d) Dispenser's Name including the name of the Dispensing Organization and Individual where applicable
(e) Dispenser's Address (Street, City, State, Zip)

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(f) Dispenser's Phone Number
(g) Dispenser's Contact Person's Name
(h) Dispenser's Chain Site ID, if available
(i) For Pharmacy Dispensers, the Pharmacy's Tennessee License Number

Patient Information

(j) ID qualifier of Patient Identifier (assigning authority)
(k) ID qualifier (identifies what type), as set forth in the CSMD Data Collection Manual
(l) ID of Patient;
(m) Patient's Name, including First, Last, and Middle names as well as Name Prefixes and Suffixes. Prefixes and Suffixes shall not be included in the First, Last, or Middle name fields. For non-human patients the last name of the patient shall be the owner's family name. The first name shall be the name of the animal.
(n) Patient Address including street address, city, state, and zip code. For non-US residents information may be collected pursuant to the instructions in the CSMD Data Collection Manual.
(o) Patient Phone Number
(p) Patient's Date of Birth; for non-human patients the Owner's Date of Birth shall be collected
(q) Patient's Gender
(r) Patient's Species
(s) Patient Location Code, if available
(t) Name of non-human patient, if applicable

Dispensing Information

(u) Reporting Status in compliance with the CSMD Data Collection Manual
(v) Prescription Number;
(w) Prescription Written Date
(x) Prescription Refills Authorized
(y) Prescription Fill Date;
(z) Prescription Refill Number;
(aa) Product ID Qualifier
(bb) Product ID
(cc) Quantity Dispensed;
(dd) Days Supply (calculated or estimated number of days the medication will cover);
(ee) Drug Dosage Units Code
(ff) Transmission Form of Prescription Origin Code
(gg) Partial Fill Indicator
(hh) Dispenser NPI Number, if available
(ii) Classification Code for Payment Type
(jj) Prescription Sold Date
(kk) RxNorm Product Qualifier

(ll) RxNorm Code
(mm) Electronic Prescription Reference and Order Number, if available
(nn) Quantity Prescribed (on the original prescription)
(oo) If a prescription contains a notation that it was written pursuant to a medical necessity
(pp) Diagnosis Code (ICD-10), if available

Prescriber Information

(qq) Prescriber's National Providers Identifier (NPI) Number, if available
(rr) Prescriber DEA number;
(ss) Prescriber DEA suffix
(tt) Prescriber last name, first name, middle name
(uu) Prescriber Phone Number
(vv) Prescriber XDEA Number
(ww) If a compound substance is dispensed, the Compound Segment of ASAP shall be used to report:
  a. Ingredient sequence Number
  b. Product ID Qualifier
  c. Product ID
  d. Compound ingredient quantity
  e. Compound drug dosage units code

(6) If the dispenser does not have an automated recordkeeping system capable of producing an electronic report of the required data in the format established by the ASAP, or for whom electronic reporting would cause an undue hardship as determined by the Committee, then that dispenser may request a waiver from the electronic reporting requirement from the Committee or its designee. The waiver may be valid for up to two (2) years from ratification by the Committee or its designee.

(7) If the Committee or its designee grants the healthcare practitioner a waiver from the electronic reporting requirement, then the dispenser shall comply with an alternative method of reporting the data as determined by the Committee or its designee, such as submitting the required data in writing on a form approved by the Committee.

(8) In reporting the appropriate payment type, the healthcare practitioner shall, where possible, report discount cards as code 99 in the Classification Code for Payment Type.

Rule 2 – Registration with the Database

(1) Each healthcare practitioner registered with the database shall register each of his or her Tennessee DEA Registration Numbers, including suffixes, as part of his or her CSMD profile.

(2) Each healthcare practitioner required by Title 63 to maintain a supervising physician shall register each and every of his or her supervising physicians within his or her CSMD profile. Each supervising physician shall be registered with the database profile within thirty (30) days after such supervisory relationship begins. Any supervising relationship which lasts less than

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thirty days in a calendar year is exempt from registration unless such registration is required for the healthcare practitioner to have the necessary access to the database.

(3) Each healthcare practitioner registered with the database must maintain a valid e-mail address associated with his or her user profile in the database.

Rule 3 – Drugs of Abuse

(1) Pursuant to TENN. CODE ANN. 53-10-308(e)(4), in addition to opioids and benzodiazepines, the Commissioner finds that Schedule II amphetamines demonstrate such a potential for abuse that when prescribing Schedule II amphetamines, all healthcare practitioners, unless otherwise exempted, shall check the controlled substance database prior to prescribing Schedule II amphetamines to a human patient at the beginning of a new episode of treatment and shall check the controlled substance database for that human patient at least semi-annually when that prescribed Schedule II amphetamine remains part of the treatment.

Rule 4 – Maintenance of Information from the CSMD by Law Enforcement Officers

(1) Information obtained from the database may be shared with other law enforcement personnel or prosecutorial officials, only upon the direction of the officer or agent who originally requested the information or such officer or agent's disclosed supervisor, and may only be shared with law enforcement personnel from other law enforcement agencies where there is a reasonable belief the information is relevant to an investigation regarding a violation of criminal law relating to controlled substances.

(2) Information obtained from the database by law enforcement personnel shall be retained by the law enforcement personnel's respective department or agency. The information obtained from the database shall not be made a public record, notwithstanding the use of the information in court for prosecution purposes. Information obtained from the database shall be maintained as evidence in accordance with each law enforcement agency's respective procedures relating to the maintenance of evidence.

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CSMD Advisory Committee's Rules

Rule 1 – Definitions of Major Physical Trauma and Severe Burn

(1) "Major Physical Trauma" means a serious injury sustained due to surgical intervention or blunt or penetrating force with the potential for serious blood loss, fracture, significant temporary or permanent impairment, disability or death.

(2) "Severe Burn" means an injury sustained from thermal or chemical causes resulting in 2nd and 3rd degree burns.

Rule 2 – Drugs of Abuse

(1) The Committee has found that Schedule V controlled substances demonstrate a potential for abuse and should be reported to the CSMD as authorized by TENN. CODE ANN. § 53-10-304. However, Schedule V controlled substances which may be dispensed without a prescription do not have to be reported to the database.

Mr. Coffman requested approval to attend the National Drug Abuse Summit in Atlanta, Georgia on April 22-25, 2019. The cost will not exceed $2,500.

- Dr. Tharpe made the motion to approve Mr. Coffman's travel to the National Drug Abuse Summit, and Dr. Dickenson seconded the motion,
- Move by acclimation Coffman's travel was approved.

Medical Director for Special Projects – Dr. Mitchell Mutter

- Dr. Mutter shared with the committee the 2019 symposia dates:
    - https://www.etsu.edu/com/cme/tndoh2018.php
    - April 4, 2019 Washington County
    - May 16, 2019 Lauderdale County
    - June 6, 2019 Anderson County
    - July 25, 2019 Johnson County
    - August 22, 2019 Polk County
    - September 5, 2019 Obion County
    - October 24, 2019 Clay County
    - November 7, 2019 Cheatham County
- Dr. Mutter discussed the TDH criteria used to determine symposia location:
    - High MME
    - Neonatal Abstinence Syndrome cases
    - Fatal and non-fatal overdoses
    - Risk factor for Hepatitis C & HIV
- Share the 2019 Chronic Pain Guidelines link: https://www.tn.gov/content/dam/tn/health/healthprofboards/pain-management-clinic/Chronic%20Pain%20Guidelines%202019.pdf
- What's different in the third edition of the Chronic Pain Guidelines:
    - Added the statement regarding methadone back into the document,
    - Added a Pediatrics Appendix,
    - Added Governor Haslam's Core Competencies,
    - Updated the Medical Treatment Guidelines for Pain Management for Workers' Compensation Selected links,
    - Removed the table for Frequently Prescribed Medications,
    - Edited the Safety Net,
    - Added a page of helpful links.

CSMD Director's Report – Dr. D. Todd Bess

- Updated the committee on his participation in the University of Tennessee College of Pharmacy and speaking schedule for 2019:
    - Franklin/January 26th & 27th
    - Kingsport/February 9th and 10th
    - Memphis/March 2nd & 3rd
    - Chattanooga/March 16th & 17th
    - Cookeville/March 30th & 31st
    - Murfreesboro/April 6th & 7th
    - Knoxville/April 13th & 14th
    - Jackson/April 27th & 28th
- Contract Update
    - TDH signed NABP contract for interstate data sharing on October 24, 2018;
    - TDH signed a long term Appriss contract on December 6, 2018
        - This contract includes new enhancements to the Tennessee CSMD.
- Tennessee currently participated in interstate data sharing with 20 states (added 7 states in 2018);
- Updated the committee on Public Chapter 1039:
    - Determined technological changes related to Partial fills, ICD-10 and Medical Necessity;
        - TN Data Collection provided by Appriss completed a critical upgrade to ASAP 4.2A (June 2017 version) on 11/15/2018;
    - Dispensers were to ensure pharmacy dispensing system compliant with the ASAP 4.2A (June 2017 version) by January 1, 2019; and
    - CSMD FAQs and the TN Data Collection Manual were updated to reflect changes in recent legislation (PC 1039) and improvements to the CSMD (posted in December 2018

at https://www.tn.gov/health/health-program-areas/health-professional-boards/csmd-board/csmd-board/faq.html.

- TDH is still working on legal agreements related to the Gateway Electronic Health Record (EHR)/Pharmacy System Integration Opportunity
    - Each human prescribing board plus the Board of Pharmacy approved the use of reserve funds to fund this project
        - Board of Medical Examiners approval on 09/26/2018;
        - Board of Podiatric Examiners approval on 09/27/2018;
        - Committee on Physician Assistants approval on 10/05/2018;
        - Board of Dentistry approval on 10/11/2018;
        - Board of Optometry approval on 10/12/2018;
        - Board of Nursing approval on 11/08/2018;
        - Board of Osteopathic Examination approval on 11/28/2018; and
        - Board of Pharmacy approval on 12/3/2018.
- Updated the committee on the 2019 Legislative Report
    - Number of registrants in 2018 was 50,991;
    - There was one search of the CSMD for every one and half prescriptions reported to CSMD in 2018, up from one search for every 14 prescriptions in 2010;
    - Doctor and pharmacy shoppers decreased 85% between 2010-2018;
    - Some interesting annual survey results:
        - 64% of prescribers have changed their treatment plan;
        - 73% of dispensers refused to fill a prescription as written;
        - 67% of respondents received a Clinical Risk Notification (CRI); and 70% felt the information was useful
            - 91% more aware of patients going to multiple prescriber
            - 60% more aware of patients going to multiple dispensers
            - 65% more aware of patients receiving highest dose of opioids.
    - The number of prescriptions for stimulants has continued to increase, growing by 51% for patients in Tennessee from 2010 to 2018; and
    - Benzodiazepines, such as alprazolam and diazepam, the data indicated a 9.5% decrease in prescriptions from 2017 to 2018.

The meeting adjourned at 10:21 a.m.